DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplement provides for changing a pathogen genus from *Pasteurella* to *Mannheimia* on labeling of florfenicol injectable solution.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569, e-mail: ndas@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, is the sponsor of NADA 141–063 that provides for use of NUFLOR (florfenicol) Injectable Solution in cattle. Schering-Plough Animal Health Corp. filed a supplemental NADA providing for changing a pathogen genus from *Pasteurella* to *Mannheimia* on product labeling. The NADA is approved as of November 8, 2001, and the regulations are amended in § 522.955 (21 CFR 522.955) to reflect the approval. Section 522.955 is also being amended to reflect an updated format. Approval of this supplemental NADA did not require review of safety or effectiveness data; therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.955 is amended by revising the section heading and by revising paragraphs (a), (d)(1)(i), (d)(1)(ii), and (d)(1)(iii) to read as follows:

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) of florfenicol.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 20 mg per kilogram (/kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(A) *Indications for use*. For treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

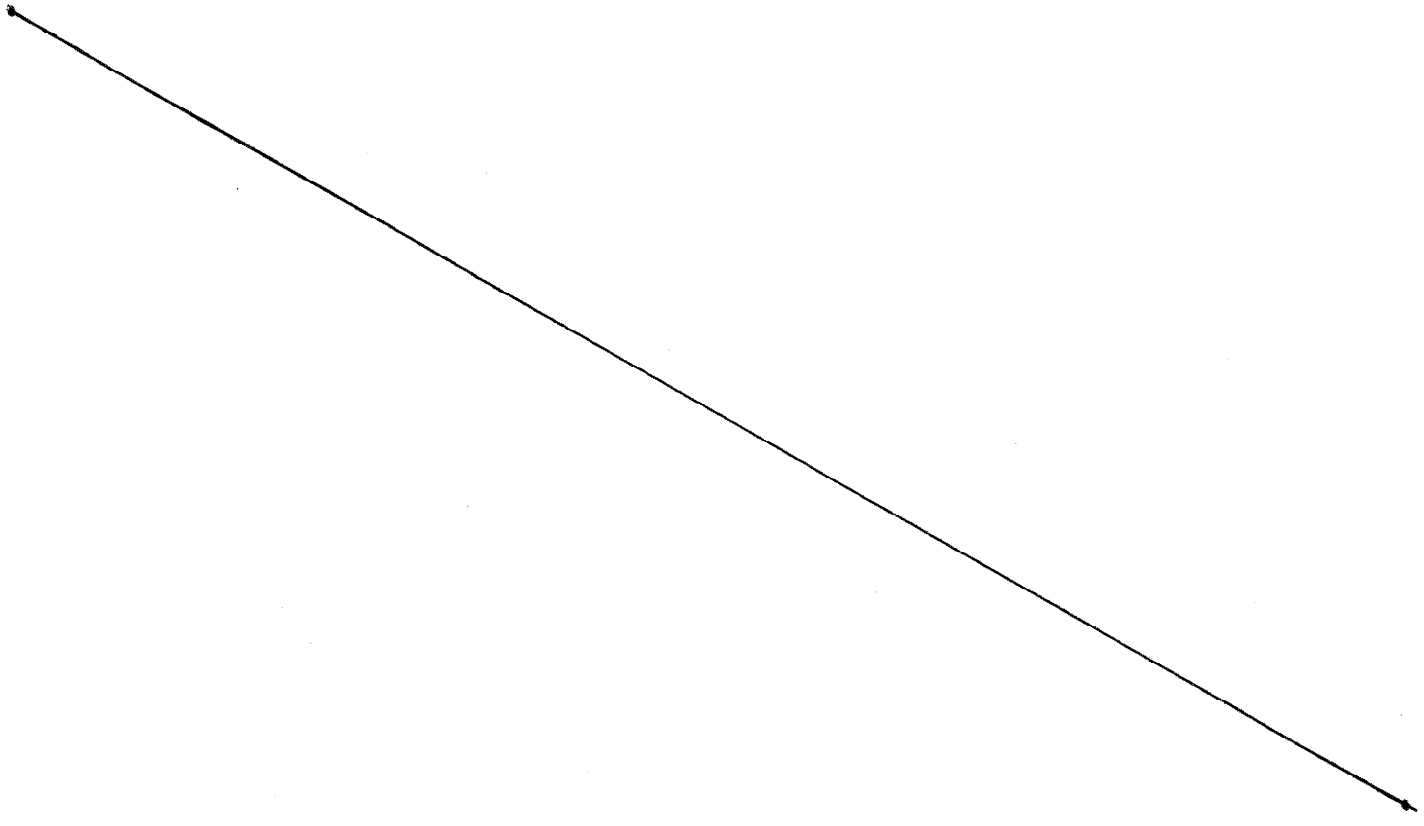
(B) [Reserved]

(ii) *Amount*. 40 mg/kg body weight as a single subcutaneous injection.

(A) *Indications for use*. As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *Limitations*. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves.



Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: Jan 31, 2002

January 31, 2002.

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation
Center for Veterinary Medicine.

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